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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,549	06/01/2000	Marianne E. Greene	ARD7001P0041US	7191

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/587,549

Applicant(s)

GREENE ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11, 16-23 and 25-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 9-11, 16-23 and 25-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☒ Other: *detailed action*.

DETAILED ACTION

Claims 9-11, 16-23, and 25-58 are pending in the case. This action is in response to the Response from applicant received 12/20/02.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 9-11 and 22, drawn to an isolated and purified peroxisome proliferator-activated receptor polypeptide, and pharmaceutical composition thereof, classified in class 530, subclass 350 and class 514, subclass 12.
- II. Claims 16 and 17, drawn to a process of making a peroxisome proliferator-activated receptor polypeptide, classified in class 435, subclass 69.1.
- III. Claims 18, 19, and 23, drawn to an antibody immunoreactive with peroxisome proliferator-activated receptor polypeptide classified in class 530 subclass 388.22.
- IV. Claim 20, drawn to a method of using an antibody to detect peroxisome proliferator activated receptor polypeptide, classified in class 435 subclass 7.21.
- V. Claims 21 and 57 are drawn to a method of detecting RNA encoding peroxisome proliferator-activated receptor polypeptide, classified in class 435, subclass 6.

- VI. Claims 25-56 are drawn to a method of screening for substances that interact with or modify the function of peroxisome proliferator-activated receptor polypeptide, classified in class 435, subclass 7.8.
- VII. Claim 58, drawn to a method of detecting DNA molecule in a biological sample which upon expression encodes a human peroxisome proliferator activated receptor gamma polypeptide, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Group I and the antibodies of Group III are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other group (each of which can be isolated from cells or organisms or made synthetically, without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Group I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made using solid-state synthesis or by isolation from a native source of the protein.

Inventions of Group I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

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the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to generate antibodies.

Inventions of Group III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a process of protein purification.

The inventions of Groups II, and IV-VII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II-VI comprise steps which are not required for or present in the methods of the other groups: transfecting a cell with a polynucleotide that encodes a peroxisome proliferator-activated receptor polypeptide (Group II), immunoreacting a peroxisome proliferator-activated receptor polypeptide with an antibody (Group IV, hybridizing messenger RNA encoding a peroxisome proliferator-activated receptor polypeptide with a polynucleotide sequence (Group V), testing the ability of a substance to interact with or modify the function of peroxisome proliferator-activated receptor polypeptide (Group VI), and hybridizing a DNA molecule from a biological sample with a polynucleotide to form a duplex, wherein said polynucleotide encodes the peroxisome proliferator-activated receptor gamma polypeptide (Group VII). The end result of the

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methods are different: production of a transformed host cell that expresses peroxisome proliferator-activated receptor polypeptide (Group II), detection of a peroxisome proliferator-activated receptor polypeptide (Group IV), detecting a messenger RNA transcript that encodes a peroxisome proliferator-activator receptor polypeptide (Group V), identification of a substance that is able to interact with or modify the function of peroxisome proliferator-activated receptor (Group VI), and the detection of a DNA molecule which upon expression encodes a human peroxisome proliferator activated receptor gamma polypeptide (Group VII). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The inventions of Group I and Groups V, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the product of Group I is not used in the methods of Groups V and VII.

The inventions of Groups III and Groups II, V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the product of Group III is not used in the methods of II and V-VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction

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for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

July 11, 2003


TERRY MCKELVEY
PRIMARY EXAMINER